

**REMARKS**

By the present amendment, claim 1 has been amended to recite that the core composition comprises at least one swelling agent, and that the swelling agent is present in the core composition in an amount such that, when the system is exposed to an aqueous environment, the swelling agent swells and exerts a pressure on the coat, thereby rupturing the coat to release contents of the core composition.

Support for the added recitation is found in the original application, for example, at least paragraphs 0100, 0108.

Further, claim 1 has been amended to recite “(d) a cover composition.” Claim 24 has also been amended to recite “the cover composition.”

Claims 1 and 3-24 are pending in the present application. Claim 1 is the only independent claim.

I. **Indefiniteness rejection**

In the Office Action, claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as indefinite. It is alleged in the Office Action that the feature “wherein the cover composition forms at least one of a plug or a band blocking the passageway” lacks antecedent basis.

Claim 1 has been amended to recite “(d) a cover composition...” which provides explicitly antecedent basis for “the cover composition” in claims 19-22.

In view of the above, it is submitted that the rejection should be withdrawn.

II. Obviousness rejection

In the Office Action, claims 1 and 3-24 are rejected under 35 U.S.C. 103(a) as obvious over US 6,004,582 to Faour et al. ("Faour") in view of US 5,229,131 to Amidon et al. ("Amidon").

Reconsideration and withdrawal of the rejection is respectfully requested. In Faour, it is essential that the coating remains intact, and that only the plug becomes detached or dissolved. Specifically, in Faour, the semipermeable membrane controls the release rate of the active ingredient via its permeability to surrounding liquid. See Faour at col. 5, lines 26-30. Thus, Faour discloses a conventional osmotic system wherein the release of the active ingredient in the core is controlled by the membrane, and accordingly, the membrane is required to be maintained intact before and throughout the release period. It is submitted that this aspect of conventional osmotic systems is well known to a person of the art.

In contrast, in the presently claimed invention, the core composition and the coat composition are designed such that, upon contact with the aqueous environment, the swelling agent present in the core composition swells and exerts a pressure on the coat, thereby rupturing the coat to release contents of the core composition, as recited in present claim 1.

It may be noted that the entry of the aqueous environment may be governed by the nature and the type of the polymer of the cover composition used to cover the passageway. That is the release of the active ingredient can be programmed depending upon the nature of the polymer in the cover composition or because of the presence of the nature of the excipients present in the core composition. For instance, when a release of the active ingredient is desired in the small

intestine, the passageway present may be covered by a polymer that is soluble only at higher pH. When the release of the active ingredient is desired in the small intestine, a polymer that is soluble in small intestine but not soluble in gastric fluids, may be used

An advantage of the presently claimed invention is that the coat is ruptured because of the pressure generated within the core due to the presence of swelling agents, so that a pulse release of the active ingredient can be provided, as discussed in the present specification.

This feature of the presently claimed invention and its advantages are not taught or suggested in Faour, which teaches away from a system wherein the rupture of the coat would be desirable, and further, Amidon fails to remedy the deficiencies of Faour. Therefore, the present claims are not obvious over Faour and Amidon taken alone or in any combination.

In addition, with respect to the dependent claims, it is submitted that the combined features of each of these respective claims are not taught or suggested by the cited references. Therefore, each of the dependent claims is not obvious over Faour and Amidon taken alone or in any combination.

In view of the above, it is submitted that the rejection should be withdrawn.

III. Anticipation rejection

In the Office Action, claims 1-3-22 and 24 are rejected under 35 U.S.C. 102(b) as anticipated by US 5,474,784 to Stevens et al. ("Stevens") as evidenced by US 5,229,131 to Amidon et al. ("Amidon").

Reconsideration and withdrawal of the rejection is respectfully requested. In Stevens, as in Faour, it is essential that the coating, i.e., the capsule remain intact and only the plug becomes

detached or dissolved. Thus, in Stevens, only the plug is degraded, whereas the impermeable portion of the coating is required to be maintained intact before and throughout the release period. See col. 1, lines 45-67.

In contrast, in the presently claimed invention, the core composition and the coat composition are designed such that, upon contact with the aqueous environment, the swelling agent present in the core composition swells and exerts a pressure on the coat, thereby rupturing the coat to release contents of the core composition, as recited in present claim 1.

An advantage of the presently claimed invention is that the coat is ruptured because of the pressure generated within the core due to the presence of swelling agents.

This feature of the presently claimed invention and its advantages are not taught or suggested in Stevens. Therefore, the present claims are not anticipated by Stevens, and not obvious over Stevens.

In addition, with respect to the dependent claims, it is submitted that the combined features of each of these respective claims are not taught or suggested by the cited references. Therefore, each of the dependent claims is not anticipated by Stevens, and not obvious over Stevens.

In view of the above, it is submitted that the rejections should be withdrawn.

#### Conclusion

In conclusion, the invention as presently claimed is patentable. It is believed that the claims are in allowable condition and a notice to that effect is earnestly requested.

Application No. **10/551,456**  
Art Unit: **1611**

Amendment under 37 CFR §1.111  
Attorney Docket No.: **053180**

If there is, in the Examiner's opinion, any outstanding issue and such issue may be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

If this paper is not considered to be timely filed, the Applicants hereby petition for an appropriate extension of the response period. Please charge the fee for such extension and any other fees which may be required to Deposit Account No. 50-2866.

Respectfully submitted,  
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